Global ISO 9000:2015

Chapter 3

ISO 9000:2015

* Have a much more significant impact than any of the quality standards
* The focus of ISO 9000:2015 is for companies to document their quality systems in a series of manuals
* It is designed to help organizations ensure they meet the needs of customers and other stakeholders
* The goal of ISO 9000:2015 is to embed a quality management system within an organization, increasing productivity, reducing unnecessary costs, and ensuring quality of processes and products.

Why ISO 9000:2015?

* Because it controls quality.
* It saves money.
* Customers expect it.
* And competitors use it.

ISO 9000 is used when you are seeking to establish a QMS that provides confidence in your organization's ability to provide products that fulfill customer needs and expectations.

ISO 9000:2015

* ISO9000:2015 is an internationally recognized Quality Management System.
* A Quality Management System (QMS) is a set of policies, processes and procedures required for planning and execution (production/development/service) in the core business area of an organization.

(i.e. areas that can impact the organization's ability to meet customer requirements.)

QMS

* Some people generically refer to the group of documents as a QMS
* It refers to the entire system - the documents just describe it.
* A QMS is nothing more than good business sense.

ISO 9000:2015

* ISO 9000:2015 does **NOT** define the actual quality of your product or service.
* ISO 9000:2015 is **NOT** a prescription for running a business
* It's just a series of good, basic business practices.
* The standard helps you achieve consistent results and continually improve the process.
* If you can make a good product ***most*** of the time, this helps you make it **all** of the time.

ISO 9000 is no more than documented common sense.

ISO

* Is the Organization for International Standards of Geneva, Switzerland
* It has a membership of 161 national standards institutes from countries large and small, industrialized and developing, in all regions of the world
* The ISO standards are very broad and nonspecific and can be adapted to many different industries

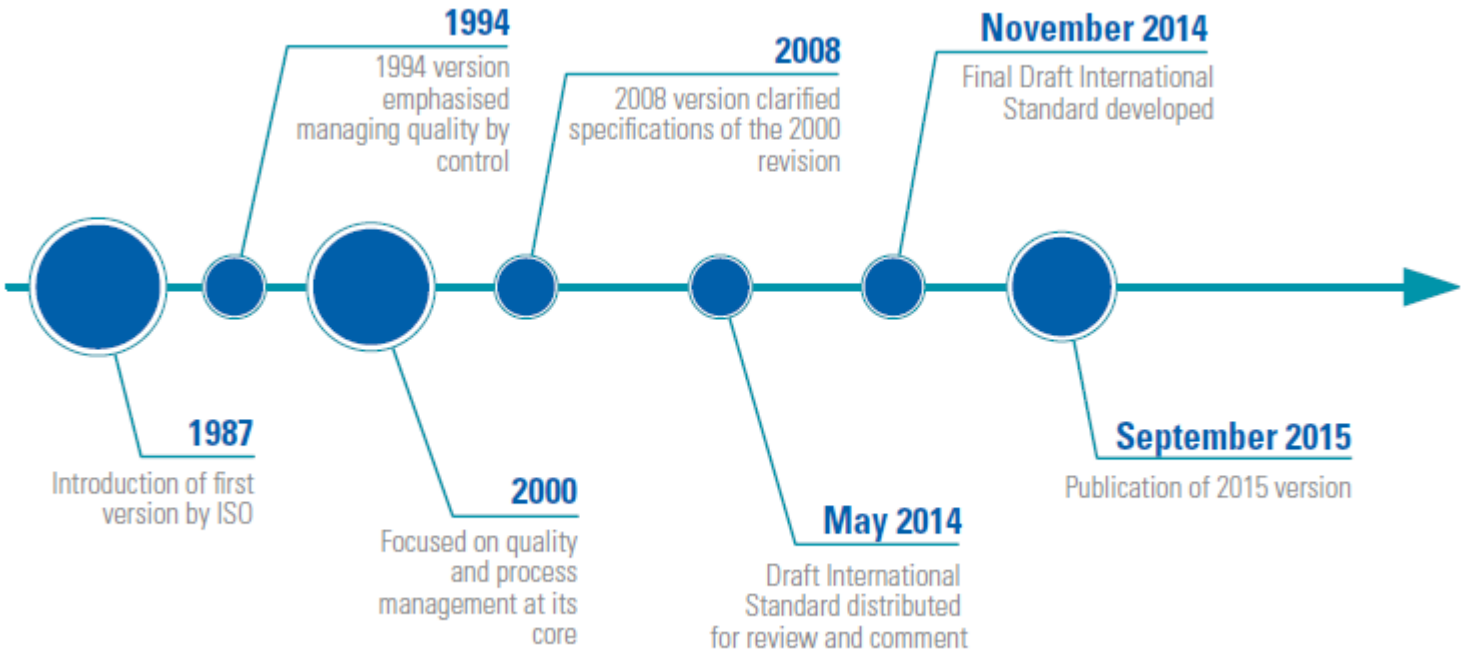
Top 10 countries for ISO 9001 certificates 2014

Rank	Country	No. of certificates
1	China	342,800
2	Italy	168,960
3	Germany	55,363
4	Japan	45,785
5	India	41,016
6	United Kingdom	40,200
7	Spain	36,005
8	USA	33,008
9	France	29,122
10	Australia	19,731

ISO 2014 survey of certifications

Standard	number of certificates in 2014	number of certificates in 2013	evolution	evolution in %
ISO 9001	1 138 155	1 126 460	11 695	1 %
ISO 14001	324 148	301 622	22 526	7 %
ISO 50001	6 778	4 826	1 952	40 %
ISO/IEC 27001	23 972	22 349	1 623	7 %
ISO 22000	30 500	26 847	3 653	14 %
ISO/TS 16949	57 950	53 723	4 227	8 %
ISO 13485	27 791	25 655	2 136	8 %
ISO 22301	1 757			
TOTAL	**1 609 294**	**1 561 482**	**47 812**	**3 %**

Evolution of ISO 9001 standard



1
New standard is proposed to relevant technical committee
If proposal is accepted
2
Working group of experts start discussion to prepare a working draft
3
1st working draft shared with technical committee and with ISO CS
If consensus is reached within the TC
4
Draft shared with all ISO national members, who are asked to comment
If consensus is reached
5
Final draft sent to all ISO members
If standard is approved by member vote
6
ISO International Standard

ISO 9000:1987

* ISO 9000:1987 had the same structure as the UK Standard BS 5750

* ISO 9001:1987 *Model for quality assurance in design, development, production, installation, and servicing* was for companies and organizations whose activities included the creation of new products.

* ISO 9002:1987 *Model for quality assurance in production, installation, and servicing* had basically the same material as ISO 9001 but without covering the creation of new products.

* ISO 9003:1987 *Model for quality assurance in final inspection and test* covered only the final inspection of finished product, with no concern for how the product was produced.

Evolution of ISO 9000

* The original version was implemented internationally in 1994
* TC 176 worked for 8 years
* By 1997 ISO 9000 family of documents had 20 required elements and 12 standards

ISO 9000:2015 has only 3 standards

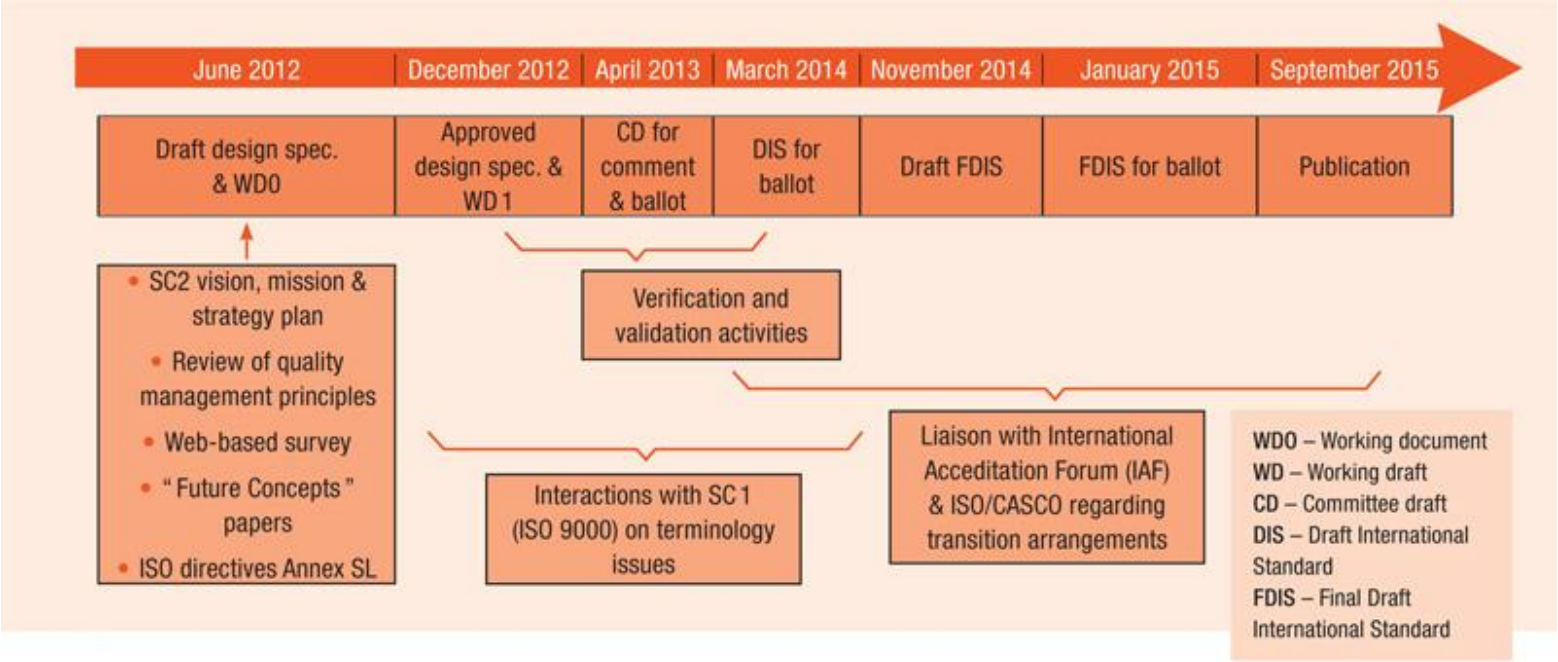
* ISO 9000:2015 – Quality management systems: Fundamentals and vocabulary
* ISO 9001:2015 – Quality management systems: Requirements
* ISO 9004:2009– Quality management: Guidelines for Performance Improvement

* ISO 9001:2015 lists requirements, while ISO 9000:2015 and ISO 9004:2009 are Quality Guidelines.

* People often say "**ISO 9000 Certified**", but what they mean is they have met the requirements of the ISO 9001 standard.

* **“ISO 9000 Certified”** is technically incorrect as ISO 9000 does not have requirements.

ISO 9001:2015



Global Supply Chain Quality and International Quality Standards

The Worldwide Way IS0 9000:2015

7 Principles:

QMP 1 – Customer focus

QMP 2 – Leadership

QMP 3 – Engagement of people

QMP 4 – Process approach

QMP 5 – Improvement

QMP 6 – Evidence-based decision making

QMP 7 – Relationship management

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What is ISO 9001?

- ISO 9001 is a standard that sets out the requirements for a quality management system.
- It helps businesses and organizations to be more efficient and improve customer satisfaction.
- A new version of the standard, ISO 9001:2015, has just been launched, replacing the previous version (ISO 9001:2008).

What is a quality management system?

- A quality management system is a way of defining **how an organization can meet the requirements** of its customers and other stakeholders affected by its work.
- ISO 9001 is based on the idea of **continual improvement**.

- It doesn't specify what the objectives relating to "quality" or "meeting customer needs" should be, but requires organizations to define these objectives themselves and continually improve their processes in order to reach them.

Who is ISO 9001 for?

- ISO 9001 is suitable for organizations of all types, sizes and sectors.
- In fact, one of the key improvements of the newly revised ISO 9001:2015 was to make it more applicable and accessible to all types of enterprises.
- Smaller companies that do not have staff dedicated to quality can still enjoy the benefits of implementing the standard – ISO has many resources to assist them.

What benefits will it bring to my business or organization?

Implementing a quality management system will help you:

- Assess the **overall context** of your organization to define who is affected by your work and what they expect from you. This will enable you to clearly **state your objectives and identify new business opportunities**.

- Put your **customers first**, making sure you consistently meet their needs and enhance their satisfaction. This can lead to repeat custom, new clients and increased business for your organization.

ISO 9001: benefits

- Work in a **more efficient way** as all your processes will be aligned and understood by everyone in the business or organization. This increases productivity and efficiency, bringing internal costs down.

- Meet the necessary **statutory and regulatory requirements**.

- **Expand into new markets,** as some sectors and clients require ISO 9001 before doing business.

- **Identify and address the risks** associated with your organization

Why was ISO 9001 revised?

- All ISO standards are reviewed and revised regularly to make sure they remain relevant to the marketplace.
- ISO 9001 has been updated to take into account the different challenges that businesses now face.
- For example, increased globalization has changed the way we do business and organizations often operate more complex supply chains, and there are increased expectations from customers.
- ISO 9001 needs to reflect these changes in order to remain relevant.

What are the key improvements?

Structure

ISO 9001:2015 now follows the same overall structure as other ISO management system standards (High-Level Structure), making it easier for anyone using multiple management systems.

Focus on risk-based thinking

This has always been part of the standard, but the new version gives it increased prominence.

What benefits does the new version bring?

The new version of the standard brings the user a number of benefits.
ISO 9001:2015:

- Puts greater emphasis on **leadership engagement**
- Helps **address organizational risks** and opportunities in a structured manner
- Uses **simplified language** and a common structure and terms, particularly helpful to organizations using multiple management systems
- Addresses **supply chain management** more effectively
- Is more **user-friendly** for service and knowledge-based organizations

Should I be certified to ISO 9001?

- Certification - when an independent certification body audits your practices against the requirements of the standard – is not a requirement of ISO 9001, but is a way of showing stakeholders that you have **implemented the standard properly**.

- For some companies, third- party certification may be a requirement. For example, some governments or public bodies may only contract suppliers that have been certified to ISO 9001.

- ISO does not perform certification.

How do I get started with ISO 9001:2015?

Key tips

Tip 1 – Define your objectives. Why do you want to implement the standard?

Tip 2 – Ensure senior management is on board. It is crucial that everyone is supportive of the initiative and its objectives. The publications *Reaping the benefits of ISO 9001* and *ISO 9001: Debunking the myths* may help with this.

Tip 3 – Identify your organization's key processes for meeting your objectives and customers' needs. Within each of these processes, ensure you understand your customers' requirements and can guarantee that these are met. This will form the basis of your quality management system.

Examples of success with ISO 9001

ISO 9001 is used successfully all over the world. In 2013 alone, over **one million certificates** to the standard were issued across 187 countries, and many other companies and organizations have used the standard without seeking certification.

Success with ISO 9001 can take many forms. For some enterprises, it is all about attracting new clients, while others see it as the blueprint for internal efficiency.

How ISO 900:2015 works?

* ISO 9000:2015 is not a rigid set of requirements, and organizations have flexibility in how they implement their quality management system.

* This freedom allows the ISO 9000 standard to be used in a wide range of organizations, and in businesses large and small.

How ISO 900:2015 works?

* ISO 9000 is its process-oriented approach.

* Instead of looking at a company's departments and individual processes, ISO 9000 requires that a company look at "the big picture."

How do processes interact?

Can they be integrated with one another?

What are the important aspects of

products and services?

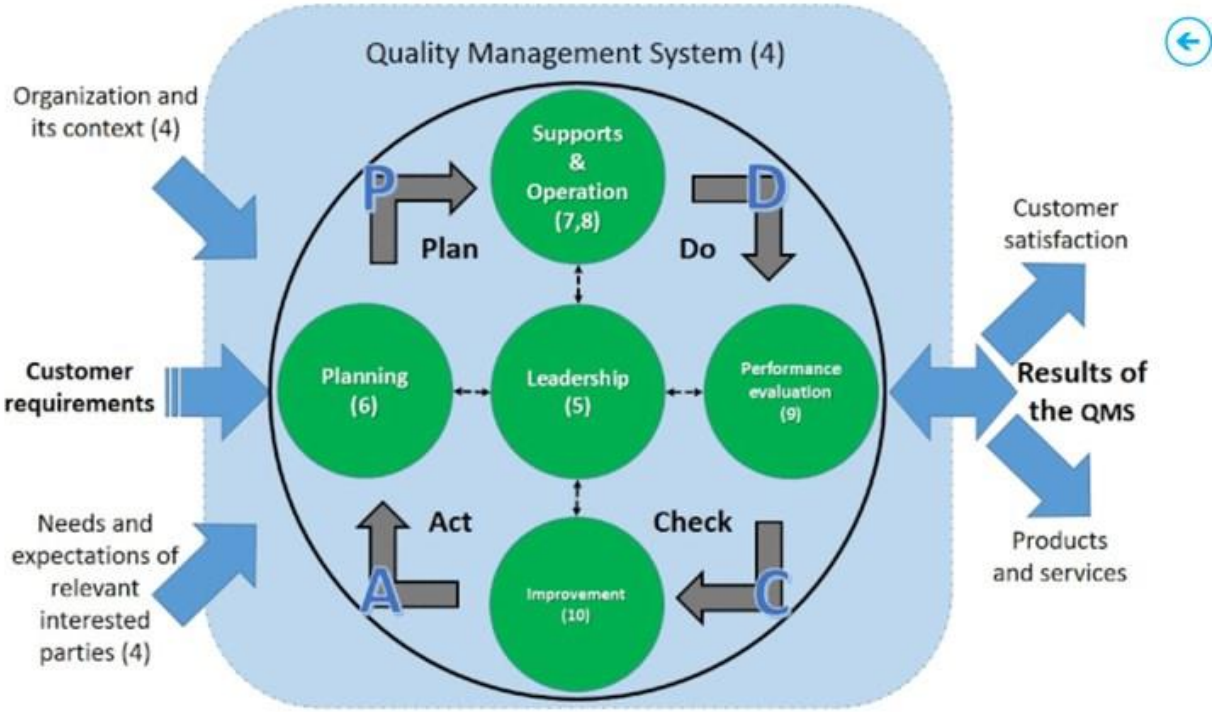
Process approach

* The elemental core of ISO's view of a Quality Management System.
* QMS can be thought of as a single large process that avails many inputs to generate many outputs.
* ISO 9001 promotes the process approach to managing an organization, and requires the QMS to consider the organization as a series of interlinked processes

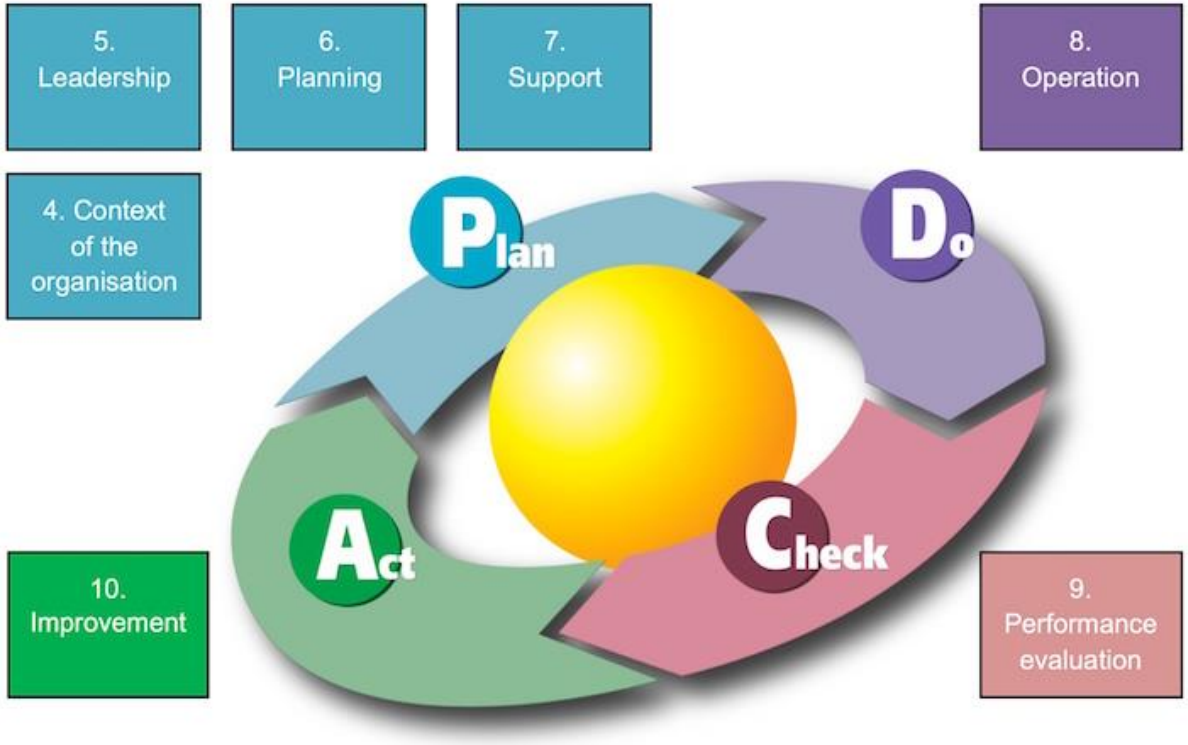
Process approach

* Every organization is made up of a series of interacting processes.
* A process is a set of activities that uses resources (people, machines, etc.) to transform inputs into outputs.
* The output of one process becomes the input of another.
* The **process approach** considers the interaction between these processes, and the inputs and outputs that tie these processes together.

PDCA


Quality Management System (4)
Organization and its context (4)
Customer requirements
Needs and expectations of relevant interested parties (4)
Supports & Operation (7,8)
P
Plan
D
Do
Planning (6)
Leadership (5)
Performance evaluation (9)
Act
A
Check
C
Improvement (10)
Customer satisfaction
Results of the QMS
Products and services

PDCA


5. Leadership
6. Planning
7. Support
8. Operation
4. Context of the organisation
Plan
Do
Act
Check
10. Improvement
9. Performance evaluation

Global Supply Chain Quality and International Quality Standards

The Worldwide Way ISO 9000:2015

Seven Clauses:

Clause 4: Context of the organization

Clause 5: Leadership

Clause 6: Planning for the quality management system

Clause 7: Support

Clause 8: Operation

Clause 9: Performance evaluation

Clause 10: Improvement

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STRUCTURE COMPARISON OF ISO 9001:2015 AND ISO 9001:2008

ISO 9001:2015	ISO 9001:2008
1. Scope	1. Scope
2. Normative references	2. Normative references
3. Terms and definitions	3. Terms and definitions
4. Context of the organisation	4. Quality management system
5. Leadership	5. Management responsibility
6. Planning	6. Resource management
7. Support	7. Product realisation
8. Operation	8. Measurement, analysis and improvement
9. Performance Evaluation	
10. Improvement	

Clause 4 – Context of the organization

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the QMS

4.4 Quality Management System and its processes

4.1 Understanding the organization and its context

Note : The concept of context of the organization is equally applicable to not-for-profit or public service organizations as it is to those seeking profits.

4.2 Understanding the needs and expectations of interested parties

Examples of Interested Parties

Interested party	Requirements	QMS processes
Customers	- Orders accurately taken - Products arrive on time - All products specifications met	- Sales and customer service process - Shipping and logistics process - Inspection process
Suppliers	- Accurate purchase order - Timely payment of invoices*	- Purchasing process - Accounts payable process*
Employees	- Clear instructions and training - Paychecks accurate and on time* - Resolution of grievances*	- Training process - Payroll process* - Human resources process*

Examples of Interested Parties

Interested party	Requirements	QMS processes
Managers	- Current information for decision making	- Management review process - Reporting on quality objectives
Owners	- Receive favorable return on investment*	- Finance process*
Community	- No excessive truck traffic*	- Shipping and logistics process
Schools and colleges	- Consideration of graduates as employees*	- Recruiting and hiring process* - Training process
Regulatory bodies	- Regulatory compliance*	- Listing of applicable regulations - Regulatory compliance process*

Examples of Interested Parties

Interested party	Requirements	QMS processes
Law enforcement	- Compliance with all laws - Reporting of illegal activities*	- Human resources process*
Emergency responders	- Reporting on dangerous substances* - Planned approach to emergencies*	- Emergency response process - Emergency maps and contact lists*
News media	- Response to request for information	- Public relations process

4.3 Determining the scope of the QMS

* **DESCRIBED IN TERMS OF:**
* products and services
* main processes involved
* sites where processes are operated

* Exclusions

4.4 Quality Management System and its processes

* NEW REQUIREMENT:
* Determination of **risks** and **opportunities**
* Plan & implement **actions** to address them
* Change to **'documented information'** lets the organization decide necessity, type and media. But previous terms, such as quality manual, procedure, record can still be used if the organization prefers them

Clause 5 - Leadership

* 5.1 Leadership and Commitment
* 5.2 Policy
* 5.3 Organizational roles, responsibilities and authorities

5.1 Leadership and Commitment

* **IMPORTANT CHANGES:**
* Top management to **establish, implement** and **maintain** quality policy
* Appropriate to the purpose **and context** of the organization
* Available to relevant interested parties, as appropriate
* Commitment to improve **the QMS**
* Communicated, understood **and applied** within the organization
* Maintained as **documented information**

Clause 6 – Planning for the QMS

* 6.1 – Actions to address risks and opportunities
* 6.2 – Quality Objectives and planning to achieve them
* 6.3 – Planning of changes

6.1 Actions to address risks and opportunities

* The emphasis is on the **planning of actions to address risks** identified as per clauses 4.1 and 4.2 .
* In a ‘note’, it is suggested that the options to address these risks may include avoidance of risk, taking the risk in order to pursue an opportunity, eliminating the source of risk, changing the likelihood or consequences of risk or acceptance of risk by informed decision.

6.3 Planning of changes

* Undertake **changes** in a planned and systematic manner
* by considering:
* Potential **consequences** of change
* Integrity of the QMS
* Availability of resources
* Allocation or reallocation of responsibilities and authorities

Clause 7 – Support

* 7.1 Resources
    - 7.1.1 General
    - 7.1.2 People
    - 7.1.3 Infrastructure
    - 7.1.4 Environment for the Operation of Processes
    - 7.1.5 Monitoring and Measuring Resources
    - 7.1.6 Organizational Knowledge
* 7.2 Competences
* 7.3 Awareness
* 7.4 Communication
* 7.5 Documented information
    - 7.5.1 General
    - 7.5.2 Creating and Updating
    - 7.5.3 Control of documented information

7.4 Communication

* ORGANIZATION NEEDS TO DETERMINE:
* • **Internal** and **external** communication needs
* • **On what** it will communicate
* • **When** to communicate
* • **With whom** to communicate
* • **How** to communicate

Clause 8 - Operation

* 81. Operation planning and control
* 8.2 Requirements for products and services
  * 8.2.1 Customer communication
  * 8.2.2 Determining the requirements related to products and services
  * 8.2.3 Review of requirements related to products and services
  * 8.2.4 Changes to requirements for products and services
* 8.3 Design and development of products and services
* 8.4 Control of externally provided processes, products and services
* 8.5 Production and service provision
* 8.6 Release of products and services
* 8.7 Control of nonconforming outputs

8.1 Operation planning and control

* Implement **planned** activities at appropriate stages to verify that product and services requirements have been met
* Delivery shall not proceed until the planned arrangements **verify conformity**, unless otherwise approved by a **relevant authority** and, where applicable, by **the customer**
* Documented information shall provide **traceability** to the **people** authorizing release of products and services for **delivery to the customer**

Clause 9 - Performance Evaluation

* 9.1 Monitoring. Measurement, analysis and evaluation
* 9.2 Internal audit
* 9.3 Management review
  * 9.3.1 General
  * 9.3.2 Management review inputs
  * 9.3.3 Management review outputs

9.1.1 General

* Implement **planned** activities at appropriate stages to verify that product and services requirements have been met
* Delivery shall not proceed until the planned arrangements **verify conformity**, unless otherwise approved by a **relevant authority** and, where applicable, by **the customer**
* Documented information shall provide **traceability** to the **people** authorizing release of products and services for **delivery to the customer**

9.2 Internal audit

* The audit program must take into account **quality objectives, customer feedback** and **changes impacting the organization**, in addition to the importance of the processes and the results of previous audits.
* Documented information must be retained as evidence of implementation of the audit programs and audit results, but there is no requirement for a documented procedure.

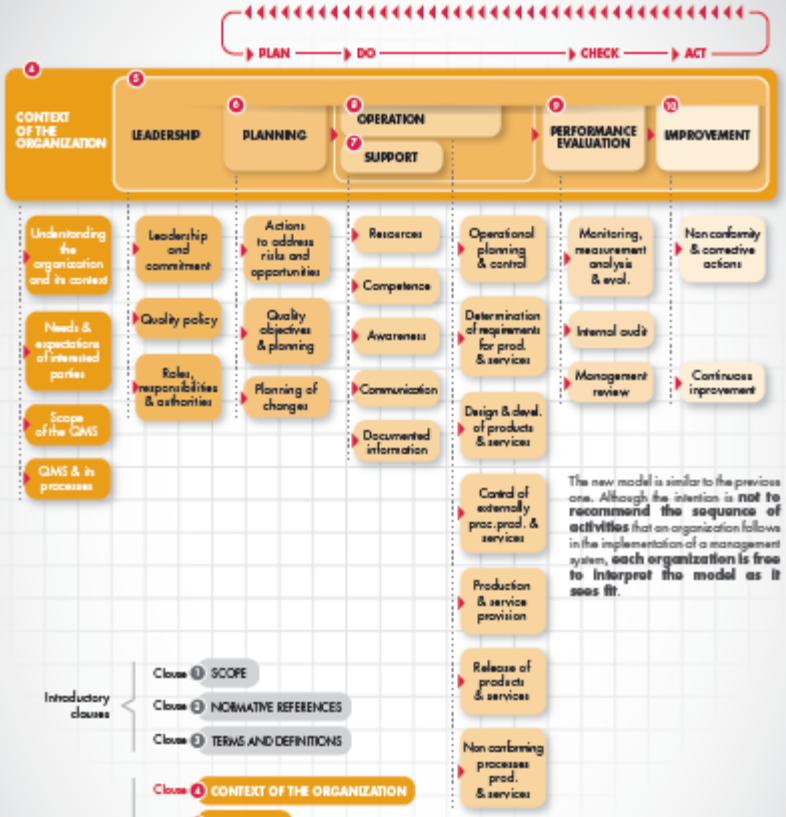
9.3 Management review

* Planned and carried out, taking into account the **changing business environment** and the **strategic direction** of the organization.
* Consider information on the **quality performance**, including **trends** and **indicators** for:
* - Non-conformities and corrective actions
* - Monitoring and measurement results
* - Audit results
* - Customer satisfaction
* - **Issues concerning external providers & interested parties**
* - **Adequacy of resources**
* - Process **performance** and conformity of products & services
* • **Effectiveness of actions to address risks & opportunities**
* • New potential opportunities for continual improvement

Clause 10 - Improvement

* 10.1 General
* 10.2 Nonconformity and corrective action
* 10.3 Continual improvement

WHAT ARE THE MAIN CHANGES IN ISO 9001?



Two of the most important objectives in the revision of the ISO 9000

* to develop a simplified set of standards that will be equally applicable to small as well as medium and large organizations, and
* for the amount and detail of documentation required to be more relevant to the desired results of the organization's process activities.

Documented Information

Documented information can be used to communicate a message, provide evidence of what was planned has actually been done, or knowledge sharing.

Some of the main objectives of an organization's documentation

* **a) Communication of Information**
* **b) Evidence of conformity**

provision of evidence that what was planned, has actually been done.

* **c) Knowledge sharing**

to disseminate and preserve the organization's experiences. A typical example would be a technical specification, which can be used as a base for design and development of a new product.

* Paper, magnetic, electronic or optical computer disc , photograph, master sample

Basic Overview

* It is easy to become overwhelmed with documentation
* Not every single process in an organization must be documented
* The 2015 revision of the standard become more liberal regarding documentation requirements

Mandatory Documents

Mandatory Documents	ISO 9001:2015 Clause
Scope of the Quality Management System	4.3
Quality Policy	5.2
Quality Objectives and Plans for Achieving Them	6.2
Procedure for Control of Externally Provided Processes, Products and Services (outsourced processes)	8.4.1

Mandatory Records

Mandatory Records	ISO 9001:2015 Clause
Record of Maintenance and Calibration of Monitoring and Measuring Equipment	7.1.5.1
Competence Records	7.2
Product/Service Requirements Review Record	8.2.3.2
Record of New Requirements for Product or Service	8.2.3.2
Design and Development Inputs Record	8.3.3

Mandatory Records

Record of Design and Development Controls	8.3.4
Design and Development Outputs Record	8.3.5
Record of Design and Development Changes	8.3.6
Record of Evaluation of External Provider (supplier)	8.4.1
Record of Product/Service Characteristics	8.5.1
Record of Changes on Customer's Property	8.5.3
Record of Changes in Production/Service Provision	8.5.6
Evidence of Product/Service Conformity	8.6
Record of Nonconformity	8.7.2, 10.2.2
Monitoring Performance Information	9.1.1
Internal Audit Program and Results	9.2.2
Management Review Results	9.3
Nonconformities and Corrective Action	10.2.2

Commonly used but not mandatory

Non-Mandatory Procedures	ISO 9001 Clause
Determining Context of the Organization and Interested Parties	4.1, 4.2
Procedure for Addressing Risks and Opportunities	6.1.
Competence, Training and Awareness Procedure	7.2, 7.3
Procedure for Control of Documents and Records	7.5

Commonly used but not mandatory

Sales Procedure	8.2
Procedure for Design and Development	8.3
Procedure for Production and Service Provision	8.5
Warehousing Procedure	8.5.4
Procedure for Measuring Customer Satisfaction	9.1.2
Procedure for Internal Audit	9.2
Procedure for Management Review	9.3
Procedure for Nonconformity and Corrective Action	10.2

* While ISO 9001 does not require that you document all of the procedures, there are several processes that are mandatory to be established in order to generate the required records

* Remember these processes and procedures are not required to be documented; however, many companies choose to do so.

One rule of thumb when deciding if you want to document a process is this:

* ***If there is a chance that the process won't be carried out as planned, then you should document it.***

* In many cases this is the best way to ensure that your Quality Management System is reliably implemented.

Quality Policy

* It is a brief statement or document that defines your quality goals and objectives, a commitment to meeting them as well as continuous improvement.

* It should provide an outline for creating, stating, and measuring your performance of the quality objectives.

Quality Policy

A-500-001-A
Form Name

QUALITY POLICY (example)

Your Company will consistently provide products and services that meet or exceed the requirements and expectations of our customers. We will actively pursue quality improvements through programs that enable each employee to do their job right the first time and every time.
(Then add measurable objectives to the company quality policy.)

President: _____

The President of *Your Company* has formulated the quality policy. The policy is explained and discussed at the general orientation training given to all new employees and has been reviewed with all current employees. All employees are expected to know what the quality policy means to them as it affects their job or position within the company. The policy is posted in prominent locations throughout the facility.

Quality Objectives

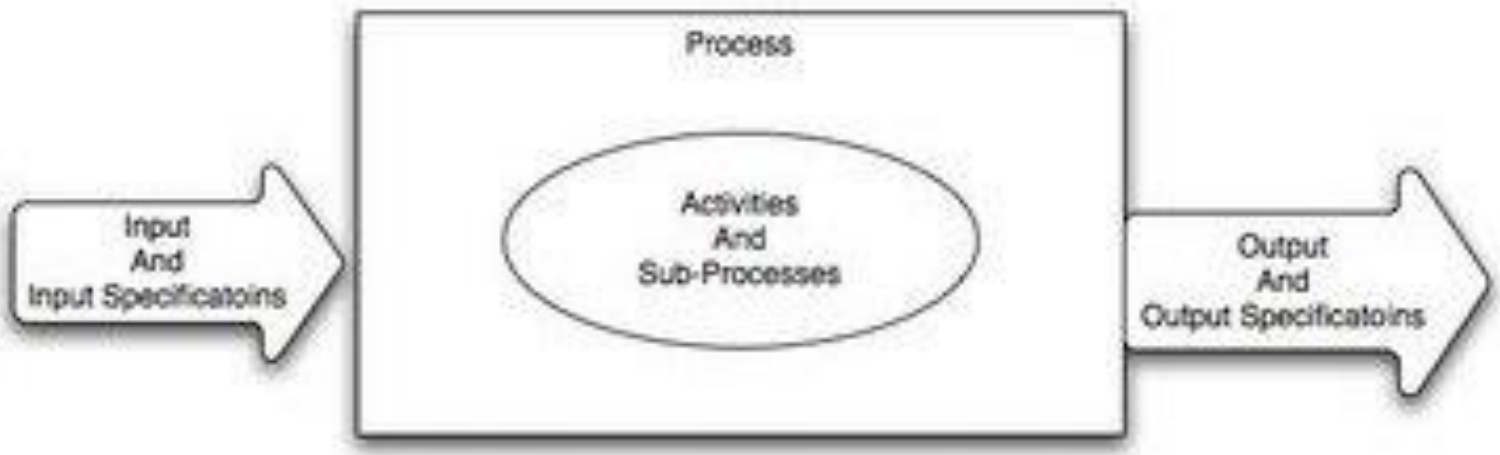
* These **measurable** steps towards achieving the QMS
* You need to ask yourself: "What will you do to meet the goals stated in the quality policy?"
* Knowing that perfection is impossible, you must have some acceptable tolerance defined and measured.
* **Examples:**
* % of on time deliveries
* % of internal scrap
* % defects

Process vs. Procedure vs. Work Instruction

* Process (Not a document)

* Process - any activity or set of activities that uses resources to transform inputs into outputs can be considered a process.

Process vs. Procedure vs. Work Instruction



Process vs. Procedure vs. Work Instruction

* **Procedures (Level 2 Documents)**
* **Procedure - *A procedure outlines how to perform a process:***

  Who performs what action

  What sequence they perform the steps in the task

  The criteria they must meet

Process vs. Procedure vs. Work Instruction

* **Work Instructions - *A work instruction describes how to perform a task*,** which is a more detailed portion of the procedure.
* You may need more detail than that described in the procedures.
* Many businesses include work instructions to aid in training, to reduce mistakes, a point of reference for jobs, etc.

A customer orders 500 parts, but only 450 are delivered

* Correction - Fix the current issue
  * Get the customer 50 more parts
* Corrective Action - Why were we short?
  * Operator miscounted 9 boxes of 50 as 10 boxes of 50
* Preventive Action - make sure it doesn't happen again
  * Weigh products on scale so you know if quantity is met

Organizations preparing to implement ISO 9001:2015

* For organizations that are in the process of implementing or have yet to implement a QMS, ISO 9001:2015 emphasizes a process approach.
* This includes:

  - Identifying the processes necessary for the effective implementation of the quality management system
  - Understanding the interactions between these processes.
  - Documenting the processes to the extent necessary to assure their effective operation and control.

(It may be appropriate to document the processes using process maps. It is emphasized, however, that documented process maps are not a requirement of ISO 9001:2015)

Organizations preparing to implement ISO 9001:2015

* These processes include the management, resource, product realization and measurement processes that are relevant to the effective operation of the QMS.
* Analysis of the processes should be the driving force for defining the amount of documentation needed for the quality management system, taking into account the requirements of ISO 9001:2015.
* It should not be the documentation that drives the processes.

Implementing ISO 9001:2015

* Step 1 – Understanding the organization and its context (Clause 4.1)
* Step 2 - Understanding the needs and expectations of interested parties (Clause 4.2)
* Step 3 – Determining the scope of the QMS (Clause 4.3)
* Step 4 – Organizational roles, responsibilities and authorities (clause 5.3)

Implementing ISO 9001:2015

* Step 5 – Develop and communicate the quality policy (Clause 5.2)
* Step 6 – Address risks and opportunities (Clause 6.1)
* Step 7 – Quality objectives and actions to achieve them (Clause 6.2)
* Step 8 – Leadership and commitment – General (Subclause 5.1.1)

Implementing ISO 9001:2015

* Step 9 – Awareness and Communication (Clauses 7.3 and 7.4)
* Step 10 – QMS and its processes (Clause 4.4)
* Step 11 – Documented information (Clause 7.5)
* Step 12 – Resources (Clauses 7.1, 7.1.1, 7.1.2, 7.1.3 and 7.1.4)
* Step 13 – Requirements for products and services (Clause 8.2)

Implementing ISO 9001:2015

* Step 14 – Control of production and service provision (Subclause 8.5.1)
* Step 15 – Design and development (Clause 8.3)
* Step 16 – Monitoring and Measuring resources (Subclause 7.1.5)
* Step 17 – Release of products and services (Clause 8.6)
* Step 18 – Control of nonconforming outputs (Clause 8.7)

Implementing ISO 9001:2015

* Step 19 – Nonconformity and corrective action (Clause 10.2)
* Step 20 – Control of externally provided processes, products, and services (Clause 8.4)
* Step 21 – Plan and control changes (Clauses 6.3 and 8.5.6)
* Step 22 – Competence (Clause 7.2)
* Step 23 – Organizational knowledge (Subclause 7.1.6)

Implementing ISO 9001:2015

* Step 24 – Monitoring, measuring, analysis and evaluation (Subclauses 9.1.1 and 9.1.3)
* Step 25 – Customer satisfacation (Subclause 9.1.2)
* Step 26 – Management review (Clause 9.3)
* Step 27 – General Improvement/Continual improvement (Clauses 10.1 and 10.3)
* Step 28 – Internal Audit (Clause 9.2)

Put your ISO 9000 QMS into Action

1. Follow documented procedures and work instructions
2. Make improvements to the processes
3. Conduct Internal Audits
4. Hold frequent Management Review meetings
5. Keep records

Checking that it works

* 1st party audit - An internal audit is a 1st party audit.
* 2nd party audit - A consumer to evaluate the performance on an organization.
* 3rd party audit - In this case, an independent certification body comes into an organization and evaluates it in terms of the ISO 9000 guidelines.
* If an organization meets the requirements of the standard, it becomes certified in ISO 9000 and carries a seal of quality recognized throughout the world.

ZERTIFIKAT ◆ CERTIFICATE ◆ СВИДЕТЕЛЬСТВО ◆ CERTIFICADO ◆ CERTIFICAT ◆ CERTIFICATO

CERTIFICATE

TÜV
MANAGEMENT SERVICE

Certificato Nr 50 100 3396

Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

RANA
DIVING & MARINE CONTRACTOR SRL
VIA A. VECCHI 7
I-48023 MARINA DI RAVENNA (RA)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO CONFORM TO THE REQUIREMENTS OF

UNI EN ISO 9001:2000

Questo certificato è valido per il seguente campo di applicazione
This certificate is valid for the following product or service range

Progettazione ed esecuzione di servizi subacquei in alto e basso fondale inerenti lavori marittimi (OG7), acquedotti, gasdotti, oleodotti (OG6) ed installazioni offshore (EA 28a)

Design and carrying out of underwater services in shallow and deep water concerning marine works(OG7), water-gas-oil pipelines (OG6) and offshore installation *(EA 28a)*

Sistema di gestione per la qualità conforme alla Norma ISO 9001:2000 valutato secondo le prescrizioni del documento SINCERT RT-05

La presente certificazione si intende riferita agli aspetti gestionali dell'impresa nel suo complesso ed è utilizzabile ai fini della qualificazione delle imprese di costruzione ai sensi dell'articolo 8 della legge 11 febbraio 1994 N. 109 e successive modificazioni e del D.P.R. 25 gennaio 2000 N. 34

Data/*date* **2003-10-16**

Data di scadenza/*Expiry date* **2006-09-19**

Lead Auditor: Massimo Pugliese

SINCERT

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.
Cinisello Balsamo (MI)

Nico Mastrorillo
Management Representative

SGS

This is a translation of
Certificate NL09/81819452
The management system of

Maron Steel Supplies B.V.

NL/DIE-900941
Campagneweg 11 C
4761 RM Zevenbergen,the Netherlands

SYSTEM CERTIFICATION
ISO 9001:2008 SGS

Has been assessed and certified as meeting the requirements of

ISO 9001:2008

Exclusions:7.3, 7.5.3, 7.5.4,7.5.5 en 7.6

For the following activities

International Project Management and Procurement services covering steel pipes, fittings, flanges bar and plate material.

This certificate is valid from 17/03/2009 to 17/03/2012.
Issue 1.

RvA
MGMT. SYS.
RvA C 055

Authorised by
Ir. J. Weide

Certification Manager

SGS Nederland B.V. Systems & Services Certification
Malledijk 18, 3208 LA Spijkenisse, Netherlands
t +31 (0)181-693333 f +31 (0)181 -693582 www.sgs.com

Page 1 of 1

SGS

SYSTEM OF INTERNATIONAL CERTIFICATION

SYSTEM OF INTERNATIONAL CERTIFICATION

CERTIFICATE

of Quality Management System
SIC.02.040.1585 dated 18.03.2016

The Certification Body "RosUkrCert" hereby certifies that the Quality Management System of

"INTEGRAL COMPLEX SYSTEMS"

LIMITED LIABILITY COMPANY
9 Boryspilska st., build. 111, Kyiv, 02099, Ukraine
EDRPOU Code 37856912

concerning:

- production assembled electronic circuit boards;
- wholesale of electronic and telecommunications equipment and parts thereto

complies with the requirements of the international standard

ISO 9001:2015

"Quality management systems. Requirements"
INTERNATIONAL STANDARD

Date of Certification: 18.03.2016
Date of Expiry: 17.03.2019

subject to annual approval
2017 – till 18.02.2017
2018 – till 18.02.2018

Head of the Certification body I. Vakulenko

ISO 9001 CERTIFIED

SIC.02.040.1585

RosUkrCert, notification certificate: SIC.02.040 dated 13.01.2015.
02192, Ukraine, Kiev, 7 Yunosti str., off. 33 Tel./Fax: +38(044)543-2395, +38(067)536-3802
issued SIC Global LLP, Suite 2, 23-24 Great James Street , London WC1N 3ES, UK

http://www.iso.org.ua
http://www.register-sic.com

Certificate

GENERIC MANAGEMENT SERVICES PVT. LTD. GMS

This Certificate is issued to

G-PMC GROUP, LLC

PO BOX 438, OXFORD, MASS 01540

after assessing the organizations Quality Management System and finding it in compliance with

ISO 9001:2015

For the following scope only :

MANUFACTURING SERVICES FOR AEROSPACE, MEDICAL, AUTOMOTIVE, PLASTICS, METALS, CHEMICALS, AND HIGH TECHNOLOGY APPLICATIONS. SUPPLIER OF MACHINED PARTS, COMPONENTS AND FABRICATED PARTS MADE FROM VARIOUS POLYMERS & - METALLICS, MANUFACTURING CONSULTATION SERVICES

Certificate No. : GMS-1215-00367

Original Certificate Date : 07th - December - 2015

Issue Date : 07th - December - 2015

Expiry Date : 06th - December - 2018

(Subject to successful surveillance audits)

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Accredited For Certification

ROMANIA RENAR

ISO/IEC 17021:2011 Accreditation Certificate No. SM 101/2013

Authorised Signature

For **Generic Management Services Pvt. Ltd.**

Kh. No. 37/15, Street No. 1, Saboli Road, Sanjay Colony, Narela, Delhi - 110 040, India

This certificate remains the property of GMS to whom it must be returned on request. This Quality System Registration is included in GMS Directory of Registered Organizations on our website "http://www.gmscert.com" for the above mention name, address & scope. By issuance of this certificate the organizations represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remain valid only above mention address and scope. This Certificate is related to the management system, not to the products or services of the certified organizations. This certificate does not provide the certified organisation with immunity from its legal obligations.

Please note that G-PMC Group is not a certification body and is independent of G-PMC Registrars. G-PMC provides manufacturing support services, representing numerous local manufacturers.

Auditing

* Two types of auditing are required to become registered to the standard: auditing by an external certification body (external audit) and audits by internal staff trained for this process (internal audits).
* The auditing process could be adequately addressed by performing "compliance auditing":
* Tell me what you do *(describe the business process)*
* Show me where it says that *(reference the procedure manuals)*
* Prove that this is what happened *(exhibit evidence in documented records)*

Internal Audit (9.2)

* An **Internal Audit** is used to assess conformity, evaluate effectiveness, and identify opportunities for improvement.
* **Internal Audits are a Quality Management System's best friend.**
* Select a group of internal auditors
* Internal audits also help company to prepare for external audits.
* During an internal audit you will compare your quality system against the requirements of the standard.

Choose your audit team

* Company should have a number of trained internal auditors for your audit program.
* Internal audit should cover each area of company once or twice a year, with an audit team of 1 to 4 auditors depending on the size of the area.
* A general guidance number is 10% of the total number of employees

(a company with 50 employees would train 5 auditors)

Prepare for Registration Audit

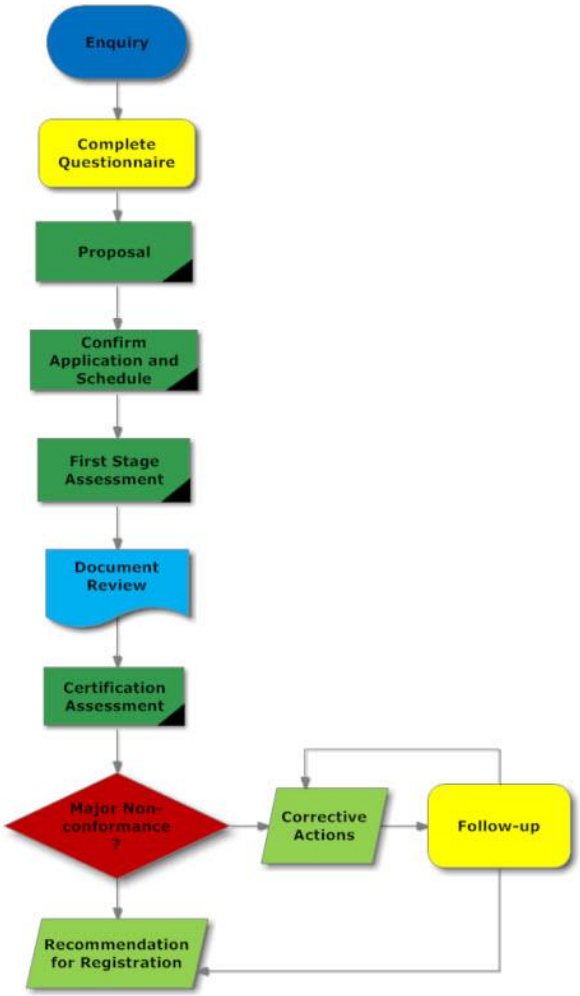
* When you choose a Registrar you are starting a relationship that will last at least 3 years, most likely longer.

* You will want to make a careful decision to lay the groundwork for a smooth and lasting relationship.

Select a Registrar (Certification Body)

* This is the most important and the messiest step of the ISO process.
* There is no central authority that qualifies ISO certification bodies.
* Many countries encourage their companies to use only ISO-registered suppliers.
* Some ISO registrars have agreements with the departments of commerce of individual countries.

ISO 9000 Registration process flow



Certification bodies

the standard in safety
EUROCAT
SGS
ICIM
Lloyd's Register
MED CERT
Professional. Flexible. Medical Only.
DNV
LRQA | Global
Measure the
Intertek
ORKI
TÜVRheinland
Precisely Right
HUNGARY
KEMA
TÜV NORD
Textile Research Ins
INSTYTUT WŁÓKIEN
SWISS TS
IN BELGIUM
NSAI
Nemko
SERTIKA
CERTIFICATION CENT
DS
CERTIFICERING
SIQ
CELOVITE
REŠITVE
PMG
CERTIQUALITY
MEYER
PREDOM
OBR
InterCert
Zertifizierungsgesellschaft mbH
TÜV SÜD
VDE
TITUTO DI CERTIFICAZIONE DELLA QUALITÀ
CERMET
Certification and
AMTAC Certification Services Limite
LNE
Le progrès, une passion à partager
our mission, you
IMQ
DEKRA
MEEI
TÜVRheinland
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QS
QUALITY SERVICE
SLG Pr
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CENTRUM BADAŃ
POLSKIE
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MPA NRW.
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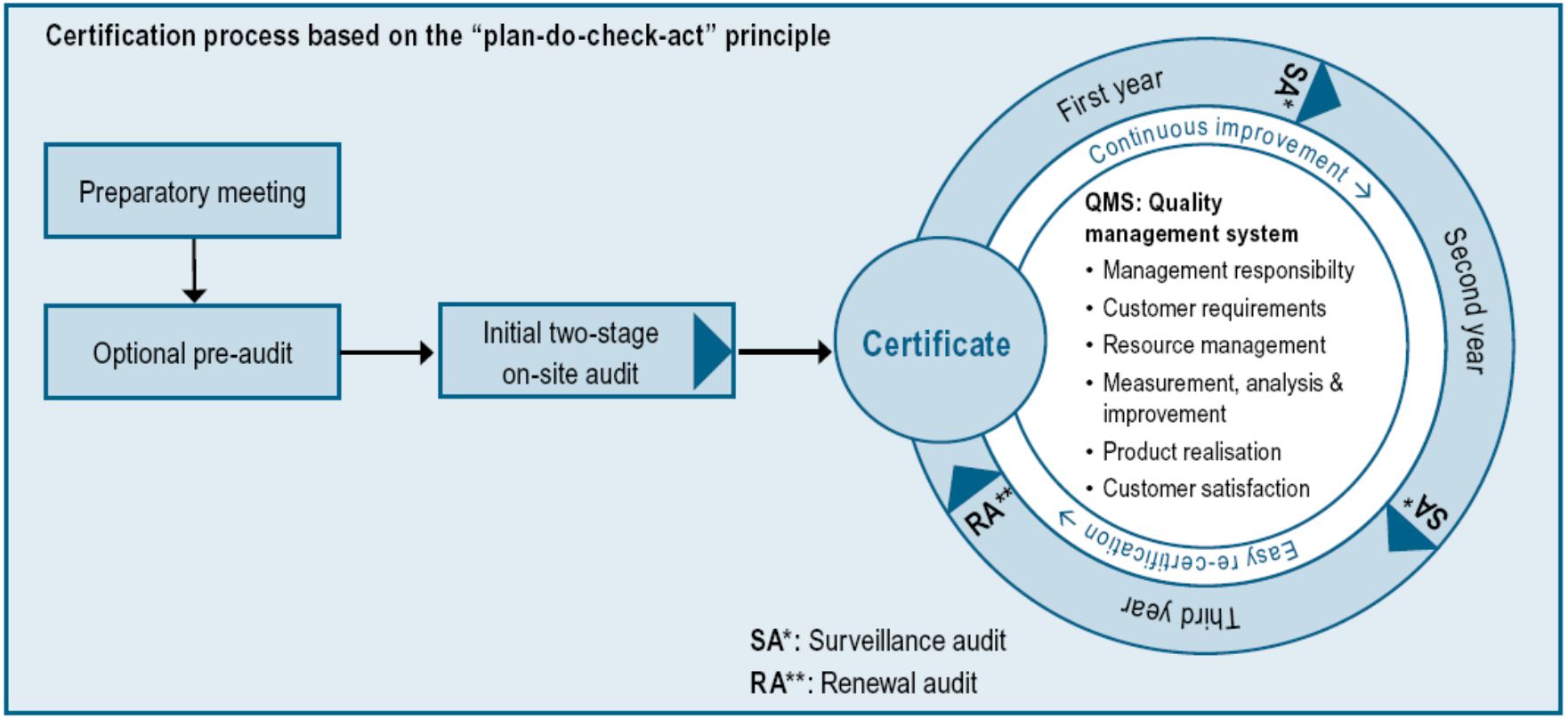
LGA
MEI
DEKRA

Certification process



Why an organization should implement ISO 9001:2015

* To keep customers satisfied, the organization needs to meet their requirements.
* The ISO 9001:2015 standard provides a **tried and tested framework** for taking **a systematic approach** to managing the organization's processes so that they consistently turn out product that satisfies customers' expectations.

Potential problems

* Amount of money, time and paperwork
* ISO 9001 promotes specification, control and procedures rather than understanding and improvement
* It "helps to mislead companies into thinking that certification means better quality"
* Certification before quality

The Chinese Way

* Historically, China was known for fine porcelain, bronze, silks and construction.
* These goods had high quality and value
* Some factors led to low quality in China
  * Low level of education
  * Lack of experience among agricultural workers who have moved into the industrial sector
  * High labor turnover
  * Workers unfamiliar with the consumer goods they are making
  * Guanxi

The Chinese Way

* The **General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ;** 中华人民共和国国家质量监督检验检疫总局) is a ministerial-level department under the State Council of the People's Republic of China
* It is in charge of national quality, metrology, entry-exit commodity inspection, entry-exit health quarantine, entry-exit animal and plant quarantine, import-export food safety, certification and accreditation, standardization , as well as administrative law enforcement.

The Chinese Way

* The **Standardization Administration of China** (**SAC;** 国家标准化管理委员会) is the Standards organization authorized by the State Council of China
* The SAC represents China within the ISO

GB standards

* **GB standards** are the Chinese national standards issued by the SAC
* *GB* stands for *Guobiao* (国标), Chinese for *national standard*.
* Mandatory standards are prefixed "GB".
* Recommended standards are prefixed "GB/T" (T from 推荐 *tuījiàn*, "recommended").
* A standard number follows "GB" or "GB/T".
* GB/T 19000-2000 is identical to ISO 9000:2000
* GB/T 24001-1996 is identical to ISO 14001:1996

中 经 认 证

QUALITY MANAGEMENT SYSTEM CERTIFICATION

Certificate

NINGBO YINZHOU HENGXING
AIR CONDITIONER FITTINGS FACTORY

REG. ADD: XIANGFENG VILLAGE, TANGXI TOWN, YINZHOU DISTRICT, NINGBO CITY, ZHEJIANG
AUDIT ADD: TONG VILLAGE,TANGXI TOWN, YINZHOU DISTRICT, NINGBO CITY, ZHEJIANG

GB/T19001-2008 idt ISO9001 : 2008 standard

MANUFACTURE OF AIR CONDITIONING REFRIGERATION PIPE FITTINGS

Date: 2009-06-22

CNAS
MANAGEMENT SYSTEM
CNAS C044- G

IAF

ISO 14000

* An international standard for environmental compliance
* ISO 14001 uses the same basic approach as ISO 9000:2015 with:
* Documentation control
* Management system auditing
* Operational control
* Control of records
* Management policies
* Audits
* Training
* Statistical techniques
* Corrective and preventive actions

The end